REMARKS

Upon entry of the foregoing amendments, claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 40-44 are pending in the instant application. In this response, claims 1, 2, 14, 16, 18, and 25 have been amended and claims 40-44 have been added. Claims 1 and 25 have been amended to more accurately claim the present invention and to further define the stringent hybridization conditions. Basis for this amendment can be found at Specification page 15, lines 3-4. Claim 1 was further amended to add a functional limitation. Basis for this amendment can be found at Specification page 12, line 22 through page 13, line 2, page 15, line 14 through page 16, line 2, and page 18, lines 6-20. Claim 14 has been amended to properly depend from claim 12. Claims 2, 16, and 18 have been amended to correct clerical errors. The claims, as amended and added herein, are fully supported by the instant specification. Support for new claims 40-41 can be found at Specification page 9, line 22 through page 10, line 6. Support for new claim 42-44 can be found at Specification page 7 lines 14-28; page 15, lines 14-28; page 19, lines 12-14; and page 21, lines 4-17. Accordingly, no new matter has been added.

DRAWINGS

Applicants acknowledge the Draftsperson's objection to the Drawings filed in the present application. In compliance with 37 CFR 1.84, Applicants have provided corrected drawings with the instant response and therefore request this objection be reconsidered and withdrawn.

SPECIFICATION - INFORMALITIES

The Examiner has objected to the specification for failing to correctly recite trademarks (TMs). Applicants have amended the specification to accurately recite trademarks in accordance with MPEP 608.01(v). Applicants believe that the present objection is now moot and should be reconsidered and withdrawn.

THE 35 U.S.C. §101 REJECTIONS

The Examiner has provisionally rejected claims 1-4, 10-14, 16, 18, 19, 25 and 26 under 35 U.S.C. §101, as claiming the same invention as that of claims 1, 20, 21, 25-28, 32-35, 41 and 42 of co-pending application No. 09/376,770 ("the '770 application"). Applicants traverse.

The '770 application is a co-pending application having the both the same inventive entity and assignee. However, both applications are directed to distinct sequences encoding different *Chlamydia* polypeptides. Applicants have attached herewith an alignment comparison between the polynucleotide of the present application with those disclosed by the '770 application (Exhibit A). The alignment comparisons clearly show that the polynucleotide according to the present invention (SEQ ID NO:1) is completely different from the polynucleotides claimed in the '770 application (SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13 and 15).

Accordingly, applicants request reconsideration and withdrawal of the present provisional double patenting rejection.

THE 35 U.S.C. §102 REJECTIONS

The Examiner has rejected claims 1 and 25 under 35 U.S.C. §102(b) as being anticipated by Longbottom *et al.* (GenEmbl Database Accession No.: U72499, 25 September 1996). Specifically, the Examiner has stated that U72499 discloses a *Chlamydia* polynucleotide comprising fragments having stretches of homology to the claimed nucleotide sequence of SEQ ID NO:1 and that such a polynucleotide or fragments thereof are capable of hybridizing with SEQ ID NO:1 under stringent conditions is inherent. Applicants traverse.

Claim 1 has been amended to delete the phrase "functional fragments thereof" and claims 1 and 25 has been amended to recite "hybridizes under stringent hybridizing conditions of 6xSSC containing 50% formamide at 42°C with SEQ ID NO:1". Furthermore, independent claim 1, from which claim 25 depends, now recites the functional limitation "wherein said isolated polynucleotide encodes a polypeptide that, when administered in an immunogenically-effective amount to a mammal, induces an immune response by said mammal against said polypeptide". U72499 does not teach expressly or inherently a sequence capable of hybridizing under the specific claimed stringent conditions to the nucleotide sequence of SEQ ID NO:1. The claims, as amended herein, further requires that the polynucleotide be capable of inducing an immune response. There is nothing in U72499 which teaches, or even suggests, polynucleotides of the present invention that are capable of inducing an immune response, as required by the claims of the present invention.

Accordingly, Applicants assert that the present application is not anticipated by Longbottom *et al.* (U72499) and request reconsideration and withdrawal of this rejection.

The Examiner has also rejected claims 1, 4, 10-13, 16, 18, 19, 25 and 26 under 35 U.S.C. §102(b) as being anticipated by Longbottom *et al.* (Infect. Immun. 66: 1317-1324, April 1998). Specifically, the Examiner has stated that Longbottom *et al.* teach "*chlamydial* genes or sequences coding for highly immunogenic protein fragments comprising 8 or 9 amino acid residues. Polynucleotide probe reagents, DNA primers, expression vectors, host cells comprising the nucleotide sequence and sequences that hybridize with the disclosed genes are taught". Applicants traverse.

As discussed *supra*, claim 1 has been amended to delete the phrase "functional fragments thereof" and claims 1 and 25 has been amended to recite "hybridizes under stringent hybridizing conditions of 6xSSC containing 50% formamide at 42°C with SEQ ID NO:1". Furthermore, independent claim 1, from which claims 4, 10-13, 16, 18, 19, 25 and 26 depend, now recites the functional limitation "wherein said isolated polynucleotide encodes a polypeptide that, when administered in an immunogenically-effective amount to a mammal, induces an immune response by said mammal against said polypeptide". Longbottom *et al.* does not teach expressly or inherently the nucleotide sequence of SEQ ID NO:1 or the polypeptide sequence of SEQ ID NO:2; polynucleotide probe reagents, DNA primers, expression vectors, or host cells comprising SEQ ID NO:1; or a sequence capable of hybridizing under the specific claimed stringent conditions to the nucleotide sequence of SEQ ID NO:1 which is capable of inducing an immune response.

Accordingly, Applicants assert that the present application is not anticipated by Longbottom *et al.* and request reconsideration and withdrawal of the present rejection.

THE 35 U.S.C. §112, FIRST PARAGRAPH REJECTIONS

The Examiner has rejected claims 39 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner states that there is no descriptive

support in the instant specification for the limitation of "said mammalian cell is a human cell." Applicants traverse.

Applicants submit that the limitation of claim 39 is fully supported by the specification. The specification discloses the use of expression cassettes to transform a eukaryotic or prokaryotic cell (*see* Specification, lines 3-12 at page 16). Moreover, Applicants specifically point to the following disclosure present in the instant application: "A recombination expression system can be selected from prokaryotic and eukaryotic hosts. Eukaryotic hosts include yeast cells (*e.g.*, *Saccharomyces cerevisiae* or *Pichia pastoris*), mammalian cells (*e.g.*, COS1, NIH3T3, or JEG3 cells), arthropods cells (*e.g.*, *Spodoptera frugiperda* (SF9) cells), and plant cells" (*See* Specification, lines 13-18 at page 16). Eukaryotic hosts include mammalian cells and mammalian cells are further represented by three cell line examples: COS-1, NIH-3T3 and JEG3 cells. The skilled artisan would recognize the origin of these cell lines. Specifically, JEG3 cells are human choriocarcinoma cells. Thus, Applicants submit that the specification discloses the use of a human cell as a eukaryotic host for a recombination expression system and the limitation in claim 39 is fully supported by the instant application.

Accordingly, Applicants request reconsideration and withdrawal of the present rejection.

The Examiner has also rejected claims 1–4, 10-14, 16, 18, 19, 25, 26, 38 and 39 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner states that the above claims are not enabled due to "the issue of uncertainty associated with the functional property of a nucleic acid encoding a polypeptide having at least 75% homology to SEQ ID NO:2" (Office Action at page 8). Applicants have amended claim 1 to delete the phrase "functional fragment thereof" and to include the functional limitation "wherein said isolated polynucleotide encodes a polypeptide that, when administered in an immunogenically-effective amount to a mammal, induces an immune response by said mammal against said polypeptide".

Applicants respectfully submit that any person skilled in the art would be able to make and use the invention commensurate in scope with this claim. Methods and computational programs for conducting sequence comparisons for homology are well known within the art. The calculation of % homology is well within the abilities of a skilled artisan and is well defined in the Specification. For example, a candidate polypeptide can be aligned with SEQ ID NO:2, as described at Specification line 14, page 10 – line 2, page 11. Once aligned, a skilled artisan simply has to determine the total number of identical amino acids shared between the candidate polypeptide and SEQ ID NO:2, divide this number by the total number of amino acids, and multiply by 100. Since the calculation of % identity does not require any algorithms, a skilled artisan can easily determine if a candidate morphogen has at least 75% of the amino acids identical with SEQ ID NO:2. Furthermore, the Specification specifically and clearly defines a "homologous amino acid sequence" *(See* Specification, line 22, page 9 – line 6, page 10) and "conservative amino acid substitutions (*See* Specification, lines 7-13 at page 10).

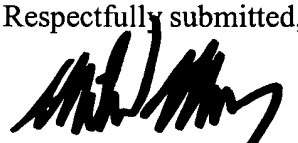
The Examiner also asserts that the Specification does not provide guidance on how any amino acid can substituted or inserted for the production of a stable polypeptide nor does the specification provide guidance on how any location can be used to produce a stable polypeptide. The functional limitation present in claim 1 should address the Examiner's concern. As amended herein, only polynucleotides that induce an immune response, when administered in an immunogenically-effective amount, fall within the scope of the claims. As such, non-functional polypeptides do not fall within the scope of the claims, as amended herein. In light of the present amendments, Applicants assert that one of ordinary skill in the art could make and use such homologous sequences in, for example, vaccines and diagnostic reagents.

Accordingly, Applicants request reconsideration and withdrawal of the present rejection.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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Dated: July 25, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The paragraph beginning on line 7 at page 27 has been replaced with the following:

-- In an ELISA assay, the product to be screened is preferably used as the coating antigen. A purified preparation is preferred, although a whole cell extract can also be used. Briefly, about 100 µl of a preparation at about 10 µg protein/ml are distributed into wells of a 96-well polycarbonate ELISA plate. The plate is incubated for 2 hours at 37°C then overnight at 4°C. The plate is washed with phosphate buffer saline (PBS) containing 0.05% [Tween 20] Tween 20™ (PBS/Tween buffer). The wells are saturated with 250 µl PBS containing 1% bovine serum albumin (BSA) to prevent non-specific antibody binding. After 1 hour incubation at 37°C, the plate is washed with PBS/Tween buffer. The antiserum is serially diluted in PBS/Tween buffer containing 0.5% BSA. 100 µl of dilutions are added per well. The plate is incubated for 90 minutes at 37°C, washed and evaluated according to standard procedures. For example, a goat anti-rabbit peroxidase conjugate is added to the wells when specific antibodies were raised in rabbits. Incubation is carried out for 90 minutes at 37°C and the plate is washed. The reaction is developed with the appropriate substrate and the reaction is measured by colorimetry (absorbance measured spectrophotometrically). Under the above experimental conditions, a positive reaction is shown by O.D. values greater than a non immune control serum. --

The paragraph beginning at line 1 at page 51 has been replaced with the following:

-- In an ELISA assay, the product to be screened is preferably used as the coating antigen. A purified preparation is preferred, although a whole cell extract can also be used. Briefly, about 100 µl of a preparation at about 10 µg protein/ml are distributed into wells of a 96-well polycarbonate ELISA plate. The plate is incubated for 2 hours at 37°C then overnight at 4°C. The plate is washed with phosphate buffer saline (PBS) containing 0.05% [Tween 20] Tween 20™ (PBS/Tween buffer). The wells are saturated with 250 µl PBS containing 1% bovine serum albumin (BSA) to prevent non-specific antibody binding. After 1 hour incubation at 37°C, the plate is washed with PBS/Tween buffer. The antiserum is serially diluted in PBS/Tween buffer containing 0.5% BSA. 100 µl of dilutions are added per well. The plate is incubated for

90 minutes at 37°C, washed and evaluated according to standard procedures. For example, a goat anti-rabbit peroxidase conjugate is added to the wells when specific antibodies were raised in rabbits. Incubation is carried out for 90 minutes at 37°C and the plate is washed. The reaction is developed with the appropriate substrate and the reaction is measured by colorimetry (absorbance measured spectrophotometrically). Under the above experimental conditions, a positive reaction is shown by O.D. values greater than a non immune control serum. --

In the Claims:

1. (Twice Amended) An isolated polynucleotide comprising a polynucleotide from a strain of *Chlamydia* selected from the group consisting of:

   (a) a polynucleotide [having a sequence] comprising the nucleotide sequence SEQ ID NO:1 [, and functional fragments thereof];

   (b) a polynucleotide encoding a polypeptide having a sequence that is at least 75% homologous to SEQ ID NO:2 [, and functional fragments thereof]; and

   (c) a polynucleotide which hybridizes under stringent hybridizing conditions of 6xSSC containing 50% formamide at 42°C [to a polynucleotide having a sequence comprising the nucleotide sequence] with SEQ ID NO:1, [and functional fragments thereof]

   wherein said isolated polynucleotide, when administered in an immunogenically-effective amount to a mammal, induces an immune response by said mammal against said strain of *Chlamydia*.

2. (Amended) The polynucleotide of claim 1, linked to a second nucleotide sequence encoding a fusion polypeptide.

14. (Amended) The host cell of claim 12 [3], wherein said host cell is a eukaryotic cell.

16. (Amended) A vaccine vector, comprising the expression cassette of claim 10.

18. (Amended) The vaccine vector of claim 16, wherein said vector is in a pharmaceutically acceptable excipient.

25. (Twice Amended) A polynucleotide probe reagent that detects the presence of *Chlamydia* in a biological material, comprising a polynucleotide that hybridizes [to] with the polynucleotide of claim 1 under stringent hybridizing conditions of 6xSSC containing 50% formamide at 42°C.

-- 40. (New) The isolated polynucleotide of claim 1, wherein the polynucleotide encodes a polypeptide having a sequence that is at least 80% homologous to SEQ ID NO:2.

41. (New) The isolated polynucleotide of claim 1, wherein the polynucleotide encodes a polypeptide having a sequence that is at least 90% homologous to SEQ ID NO:2.

42. (New) The vaccine vector of claim 16, wherein said vector is a viral live vaccine vector or a bacterial live vaccine vector.

43. (New) The vaccine vector of claim 42, wherein said viral live vaccine vector is selected from the group consisting of: adenoviruses, alphavirus, and poxviruses.

44. (New) The vaccine vector of claim 42, wherein said bacterial live vaccine vector is selected from the group consisting of: *Shigella, Salmonella, Vibrio cholerae, Lactobacillus*, Bacille bilié de Calmette-Guérin, and *Streptococcus*. --